(Rel 85—11/00 - Pub 605) FORM 9-37 9-221

Practitioner's Docket No. IKU 0102 PUSA **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Kenji Sakamoto

Application No.: 0 9 / 269,703 Group No.: 1646
Filed: February 2, 2000 Examiner: John Ulm
For: METHOD OF SEARCHING FOR PHYSIOLOGICALLY ACTIVE SUBSTANCES AND PROCESS FOR PRODUCING THE SAME

Box Sequence
Assistant Commissioner for Patents
Washington, D.C. 20231

SUBMISSION OF "SEQUENCE LISTING," COMPUTER READABLE COPY, AND/OR AMENDMENT PERTAINING THERETO FOR BIOTECHNOLOGY INVENTION CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE

(check and complete this item, if applicable)

1. ☒ This replies to the Office Letter dated February 26, 2001.

NOTE: If these papers are filed before the office letter issues, adequate identification of the original papers should be made, e.g., in addition to the name of the inventor and title of invention, the filing date based on the "Express Mail" procedure, the application number from the return post card or the attorney's docket number added.

☒ A copy of the Office Letter is enclosed.

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10*
*(When using Express Mail, the Express Mail label number is **mandatory**; Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231

37 C.F.R. § 1.8(a)

☒ with sufficient postage as first class mail.

37 C.F.R. § 1.10*

☐ as "Express Mail Post Office to Addressee"
Mailing Label No. _____ **(mandatory)**

TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office.

Donna L. Schulte
Signature

Date: 3/21/01

DONNA SCHULTE
(type or print name of person certifying)

***WARNING:** *Each paper or fee filed by Express Mail **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).*
*"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.*

IDENTIFICATION OF PERSON MAKING STATEMENT

2. I, James N. Kallis
(type or print name of declarant signing below)
state the following:

ITEMS BEING SUBMITTED

3. Submitted herewith is/are:

(check each item as applicable)

A. ☒ "Sequence Listing(s)" for the nucleotide and/or amino acid sequence(s) in this application. Each "Sequence Listing" is assigned a separate identifier as required in 37 C.F.R. § 1.821(c) and 37 C.F.R. §§ 1.822 and 1.823.

B. ☐ An amendment to the description and/or claims, wherein reference is made to the sequence by use of the assigned identifier, as required in 37 C.F.R. § 1.821(d).

C. ☒ A copy of each "Sequence Listing" submitted for this application in computer readable form, in accordance with the requirements of 37 C.F.R. §§ 1.821(e) and 1.824.

D. ☐ Please transfer to this application, in accordance with 37 C.F.R. § 1.821(e), the computer readable copy(ies) from applicant's other application identified as follows:

In re application of:

Application No.: 0 / Group No.:
Filed: Examiner:
For:

The Computer readable form(s) of applicant's other application corresponds to the "Sequence Indentifier(s)" of the application as follows:

Computer Readable Form (other application)	"Sequence Identifier" (this application)

NOTE: *"If the computer readable form of a new application is to be identical with the computer readable form of another application of the applicant on file in the Office, reference may be made to the other application and computer readable form in lieu of filing a duplicate computer readable form in the new application. The new application shall be accompanied by a letter making such reference to the other application and computer readable form, both of which shall be completely identified." 37 C.F.R. § 1.821(e).*

E. ☒ A statement that the content of each "Sequence Listing" submitted and each computer readable copy are the same, as required in 37 C.F.R. § 1.821(g).

☐ Because the statement is not made by a person registered to practice before the Office, the statement is verified as required in 37 C.F.R. § 1.821(b).

F. ☒ Because this submission is made in fulfilling the requirement under 37 C.F.R. § 1.821(g), a statement that the submission includes no new matter.

☐ Because the statement is not made by a person registered to practice before the Office, the statement is verified, as required in 37 C.F.R. § 1.821(g).

STATEMENT THAT "SEQUENCE LISTING" AND COMPUTER READABLE COPY ARE THE SAME AND/OR THAT PAPERS SUBMITTED INCLUDES NO NEW MATTER

4. I hereby state:

(complete applicable item A and/or B)

A. ☒ Each computer readable form submitted in this application, including those forms requested to be transferred from applicant's other application, is the same as the "Sequence Listing" to which it is indicated to relate.

B. ☐ All papers accompanying this submission, or for which a request for transfer from applicants' other application, introduce no new matter.

STATUS

5. Applicant is

☒ a small entity. A statement:

☐ is attached.

☒ was already filed.

☐ other than a small entity.

EXTENSION OF TERM

6.

NOTE: "Extension of Time in Patent Cases (Supplement Amendments)—If a timely and complete response has been filed after a Non-Final Office Action, an extension of time is not required to permit filing and/or entry of an additional amendment after expiration of the shortened statutory period.

If a timely response has been filed after a Final Office Action, an extension of time is required to permit filing and/or entry of a Notice of Appeal or filing and/or entry of an additional amendment after expiration of the shortened statutory period unless the timely-filed response placed the application in condition for allowance. Of course, if a Notice of Appeal has been filed within the shortened statutory period, the period has ceased to run." Notice of Dec. 10, 1985 (1061 O.G. 34-35).

NOTE: See 37 C.F.R. § 1.645 for extensions of time in interference proceedings and 37 C.F.R. § 1.550(c) for extensions of time in reexamination proceedings.

7. The proceedings herein are for a patent application and the provisions of 37 C.F.R. § 1.136 apply.

(complete (a) or (b) as applicable)

(a) ☐ Applicant petitions for an extension of time under 37 C.F.R. § 1.136 (fees: 37 C.F.R. § 1.17(a)(1)-(4)) for the total number of months checked below:

Extension (months)	Fee for other than small entity	Fee for small entity
☐ one month	$ 110.00	$ 55.00
☐ two months	$ 390.00	$ 195.00
☐ three months	$ 890.00	$ 445.00
☐ four months	$ 1,390.00	$ 695.00

Fee: $0.00

If an additional extension of time is required, please consider this a petition therefor.

(check and complete the next item, if applicable)

☐ An extension for _____ months has already been secured. The fee paid therefor of $_____ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request $_____

OR

(b) ☒ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition for extension of time.

FEE PAYMENT

8. ☐ Attached is a ☐ check ☐ money order in the amount of $ _____

☐ Authorization is hereby made to charge the amount of $ _____

☐ to Deposit Account No. _____

☐ to Credit card as shown on the attached credit card information authorization form PTO-2038.

WARNING: *Credit card information should **not** be included on this form as it may become public.*

☐ Charge any additional fees required by this paper or credit any overpayment in the manner authorized above.

A duplicate of this paper is attached.

FEE DEFICIENCY

9.

NOTE: If there is a fee deficiency and there is no authorization to charge an account, additional fees are necessary to cover the additional time consumed in making up the original deficiency. If the maximum, six-month period has expired before the deficiency is noted and corrected, the application is held abandoned. In those instances where authorization to charge is included, processing delays are encountered in returning the papers to the PTO Finance Branch in order to apply these charges prior to action on the cases. Authorization to charge the deposit account for any fee deficiency should be checked. See the Notice of April 7, 1986, 1065 O.G. 31-33.

10. ☒ If any additional extension and/or fee is required, charge

☒ Deposit Account No. 02-3978

☐ Credit card as shown on the attached credit card information authorization form PTO-2038.

WARNING: *Credit card information should **not** be included on this form as it may become public.*

SIGNATURE(s)

MARCH 21, 2001
Date

1000 Town Center, 22nd Floor
P.O. Address of Signatory
Southfield, MI 48075

(if applicable)
Telephone No. (248) 358-4400
Reg. No. 41,102
Customer No.:

JAMES N. KALLIS
(type or print name of person signing statement)

(signature)

☐ Inventor(s)
☐ Assignee of complete interest
☐ Person authorized to sign on behalf of assignee
☒ Practitioner of record
☐ Filed under Rule 34(a)
☐ Registration No. _____
☐ Other _____
(specify identity of declarant)

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/269,703	02/02/00	SAKAMOTO	

EXAMINER	
ART UNIT	PAPER NUMBER
	12

HM22/0326

JAMES N KALLIS
BROOKS & KUSHMAN
1000 TOWN CENTER
22ND FLOOR
SOUTHFIELD MI 48075

DATE MAILED:

COPY Dm 3-26-01 S.O

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: Commissioner of Patents and Trademarks
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	12

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). A computer readable form (CRF) of the sequence listing was submitted. However, the CRF could not be processed by the Scientific and Technical Information Center (STIC) for the reason(s) set forth on the attached RAW SEQUENCE LISTING ERROR REPORT.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached RAW SEQUENCE LISTING ERROR REPORT.

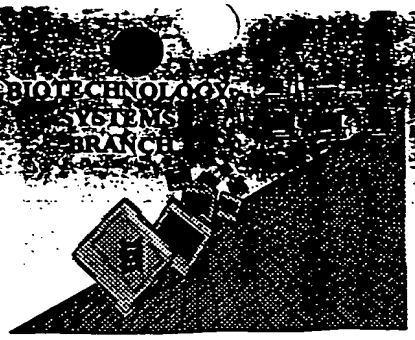
Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800



RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 09/269,703

Source: 1646

Date Processed by STIC: 2/5/2001

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.
PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

1) **INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,**
2) **TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY**

FOR CRF SUBMISSION QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

FOR SEQUENCE RULES INTERPRETATION, PLEASE CONTACT ROBERT WAX, 703-308-4216.
PATENTIN 2.1 e-mail help: patin21help@uspto.gov or phone 703-306-4119 (R. Wax)
PATENTIN 3.0 e-mail help: patin3help@uspto.gov or phone 703-306-4119 (R. Wax)

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 3.0 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW:

Checker Version 3.0

The Checker Version 3.0 application is a state-of the-art Windows based software program employing a logical and intuitive user-interface to check whether a sequence listing is in compliance with format and content rules. Checker Version 3.0 works for sequence listings generated for the original version of 37 CFR §§1.821 – 1.825 effective October 1, 1990 (old rules) and the revised version (new rules) effective July 1, 1998 as well as World Intellectual Property Organization (WIPO) Standard ST.25.
Checker Version 3.0 replaces the previous DOS-based version of Checker, and is Y2K-compliant. Checker allows public users to check sequence listings in Computer Readable form (CRF) before submitting them to the United States Patent and Trademark Office (USPTO). Use of Checker prior to filing the sequence listing is expected to result in fewer errored sequence listings, thus saving time and money.

Checker Version 3.0 can be down loaded from the USPTO website at the following address:

http://www.uspto.gov/web/offices/pac/checker

1646

RAW SEQUENCE LISTING
PATENT APPLICATION: US/09/269,703

DATE: 02/05/2001
TIME: 13:26:36

Input Set : A:\es.txt
Output Set: N:\CRF3\02052001\I269703.raw

Does Not Comply
Corrected Diskette Needed

```
 3 <110> APPLICANT: Sakamoto, Kenji
 5 <120> TITLE OF INVENTION: Method for identifying physiologically active peptides and production sam
 7 <130> FILE REFERENCE: F6001G/PUSA
 9 <140> CURRENT APPLICATION NUMBER: US 09/269,703
10 <141> CURRENT FILING DATE: 2000-02-02
12 <150> PRIOR APPLICATION NUMBER: PCT/JP97/03499
13 <151> PRIOR FILING DATE: 1997-10-01
15 <160> NUMBER OF SEQ ID NOS: 3
17 <170> SOFTWARE: Patentin version 3.0
19 <210> SEQ ID NO: 1
20 <211> LENGTH: 16
21 <212> TYPE: PRT
22 <213> ORGANISM: peptide
24 <400> SEQUENCE: 1
26 Lys Leu Thr Thr Ile Phe Pro Leu Asn Trp Lys Tyr Arg Lys Ala Leu
27 1               5                  10                  15
29 <210> SEQ ID NO: 2
30 <211> LENGTH: 27
31 <212> TYPE: PRT
32 <213> ORGANISM: peptide
34 <400> SEQUENCE: 2
36 Gly Asn Gly Val Val Ser Ala Trp Glu Ala Gln Gly Ala Lys Ser Gly
37 1               5                  10                  15
39 Ser Gly Leu Thr Arg Ala Tyr Thr His Val Pro
40             20                  25
42 <210> SEQ ID NO: 3
43 <211> LENGTH: 12
44 <212> TYPE: PRT
45 <213> ORGANISM: peptide
47 <400> SEQUENCE: 3
49 Pro Ser Cys Gln Trp Val Gln Ala Pro Ala Cys Gln
50 1               5                  10
```

invalid response - per 1.823 of new Sequence Rules, the only valid <2137 responses are: Unknown, Artificial Sequence, or scientific name (Genus/species) (one of the three) (see circled portion of Item 12 on Error Summary Sheet)

VERIFICATION SUMMARY
PATENT APPLICATION: US/09/269,703

DATE: 02/05/2001
TIME: 13:20:37

Input Set : A:\es.txt
Output Set: N:\CRF3\02052001\I269703.raw

Raw Sequence Listing Error Summary

ERROR DETECTED **SUGGESTED CORRECTION** SERIAL NUMBER: 09/269,703

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

1 ____ Wrapped Nucleics
The number/text at the end of each line "wrapped" down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".

2 ____ Wrapped Aminos
The amino acid number/text at the end of each line "wrapped " down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".

3 ____ Incorrect Line Length
The rules require that a line not exceed 72 characters in length. This includes spaces.

4 ____ Misaligned Amino Acid Numbering
The numbering under each 5th amino acid is misaligned. This may be caused by the use of tabs between the numbering. It is recommended to delete any tabs and use spacing between the numbers.

5 ____ Non-ASCII
This file was not saved in ASCII (DOS) text, as required by the Sequence Rules.
Please ensure your subsequent submission is saved in ASCII text so that it can be processed.

6 ____ Variable Length
Sequence(s) ____ contain n's or Xaa's which represented more than one residue.
As per the rules, each n or Xaa can only represent a single residue.
Please present the maximum number of each residue having variable length and indicate in the (ix) feature section that some may be missing.

7 ____ PatentIn ver. 2.0 "bug"
A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequence(s) _____. Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. **This applies primarily to the mandatory <220>-<223> sections for Artificial or Unknown sequences.**

8 ____ Skipped Sequences (OLD RULES)
Sequence(s) ____ missing. If intentional, please use the following format for each skipped sequence:
(2) INFORMATION FOR SEQ ID NO:X:
(i) SEQUENCE CHARACTERISTICS:(Do not insert any headings under "SEQUENCE CHARACTERISTICS")
(xi) SEQUENCE DESCRIPTION:SEQ ID NO:X:
This sequence is intentionally skipped

Please also adjust the "(iii) NUMBER OF SEQUENCES:" response to include the skipped sequence(s).

9 ____ Skipped Sequences (NEW RULES)
Sequence(s) ____ missing. If intentional, please use the following format for each skipped sequence.
<210> sequence id number
<400> sequence id number
000

10 ____ Use of n's or Xaa's (NEW RULES)
Use of n's and/or Xaa's have been detected in the Sequence Listing.
Use of <220> to <223> is MANDATORY if n's or Xaa's are present.
In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.

11 ____ Use of <213>Organism (NEW RULES)
Sequence(s) _____ are missing this mandatory field or its response.

12 ____ Use of <220>Feature (NEW RULES)
Sequence(s) ____ are missing the <220>Feature and associated headings.
Use of <220> to <223> is MANDATORY if <213>ORGANISM is "Artificial" or "Unknown"
Please explain source of genetic material in <220> to <223> section.
(See "Federal Register," 6/01/98, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of new Rules)

13 ____ PatentIn ver. 2.0 "bug"
Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other means to copy file to floppy disk.

COUNT SHEET FOR SEQUENCE CASES

Serial No. _____ AE _____

Date of Count _____

Mark only one space below

_____ **(CRFN)** (CRF is unreadable; use CRF Diskette Problem Report)

_____ **(CRFD)** (CRF does not comply; use Notice to Comply)

_____ **(CRFR)** (CRF required but none submitted; use Notice to Comply)

_____ **(bona fide)** (second or subsequent letter to applicant reporting bona fide attempt to comply; use Notice to Comply and send copy of RSL)

_____ **(non bona fide)** (second or subsequent letter to applicant reporting non-bona fide attempt to comply; use Notice to Comply and send copy of RSL)

Examiner's Name:_____ GAU:_____